

70
AF

PTO/SB/21 (12-07)

Approved for use through 12/31/2007. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

Application Number 09/931,466

Filing Date 8/16/2001

First Named Inventor L. Paskar

Art Unit 3762

Examiner Name M. Bockelman

Attorney Docket Number 74442.01

ENCLOSURES (Check all that apply)

<input type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance Communication to TC
<input type="checkbox"/> Fee Attached	<input type="checkbox"/> Licensing-related Papers	<input checked="" type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
<input type="checkbox"/> Amendment/Reply	<input type="checkbox"/> Petition	<input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)
<input type="checkbox"/> After Final	<input type="checkbox"/> Petition to Convert to a Provisional Application	<input type="checkbox"/> Proprietary Information
<input type="checkbox"/> Affidavits/declaration(s)	<input type="checkbox"/> Power of Attorney, Revocation	<input type="checkbox"/> Status Letter
<input type="checkbox"/> Extension of Time Request	<input type="checkbox"/> Change of Correspondence Address	<input type="checkbox"/> Other Enclosure(s) (please identify below):
<input type="checkbox"/> Express Abandonment Request	<input type="checkbox"/> Terminal Disclaimer	
<input type="checkbox"/> Information Disclosure Statement	<input type="checkbox"/> Request for Refund	
<input type="checkbox"/> Certified Copy of Priority Document(s)	<input type="checkbox"/> CD, Number of CD(s) _____	
<input type="checkbox"/> Reply to Missing Parts/Incomplete Application	<input type="checkbox"/> Landscape Table on CD	
<input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53	Remarks	
	Reply Brief	

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Gregory E. Upchurch		
Signature			
Printed name	Gregory E. Upchurch		
Date	12/26/07	Reg. No.	28,482

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature			
Typed or printed name	Gregory E. Upchurch	Date	12/26/07

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: L. Paskar

SERIAL NO.: 09/931,466

FILED: 8/16/2001

FOR: Catheter with Out-of-plane
Configurations

GROUP ART UNIT: 3762

EXAMINER: M. Bockelman

DOCKET NO.: 74442.01

Confirmation No. 3794

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Attention: Board of Patent Appeals and Interferences

APPELLANT'S REPLY BRIEF

In response to the Examiner's Answer dated October 30, 2007, Applicant L. Paskar, M.D., submits the following reply brief. Applicant L. Paskar, M.D., has addressed the issues raised in the Examiner's Answer and has not added any new subject matter in this reply brief.

This reply brief is being filed within two months of the date of the Examiner's Answer, so no fee is believed to be required.

TABLE OF CONTENTS

I.	STATUS OF CLAIMS	3
II.	GROUND OF REJECTION TO BE REVIEWED ON APPEAL	4
III.	ARGUMENT	6

I. STATUS OF CLAIMS

The status of the claims in this application is the total number of claims in application

The total claims in the application are 1-34.

Status of the Claims

1. Claims cancelled: 1-18, 23, 25, 27, 30, 31, 33 & 34.
2. Claims withdrawn from consideration but not cancelled: none.
3. Claims pending: 19-22, 24, 26, 28, 29, & 32.
4. Claims allowed: None.
5. Claims rejected: 19-22, 24, 26, 28, 29, & 32.

Claims on Appeal

The claims on appeal are 19-22, 24, 26, 28, 29, & 32.

II. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Whether claims 19-22 are unpatentable under 35 U.S.C. 102(b) over U.S. Patent 4,430,083 to Ganz et al.

Whether claims 24, 26, 28, and 32 are unpatentable under 35 U.S.C. § 103(a) over U.S. Patent 4,430,083 to Ganz et al. in view of U.S. Patent 3,970,089 to Saice.

Whether claims 19-22 are unpatentable under 35 U.S.C. § 102(b) as anticipated by (or in the alternative under 35 U.S.C. 103(a)) over Sylvanowicz (U.S. Pat. No. 5,267,982), alone or in view of either Voda (U.S. Pat. No. 5,445,625) or Weldon U.S. Pat. No. 5,195,990) and Kiemeneij (U.S. Pat. No. 6,723,083).

Whether claims 22, 24, 26, 28, 29, and 32 are unpatentable under 35 U.S.C. § 102(b) as anticipated by (or in the alternative under 35 U.S.C. 103(a)) over Sylvanowicz (U.S. Pat. No. 5,267,982), alone or in view of Voda U.S. Pat. No. 5,401,258 and optionally in view of Saice (U.S. Patent 3,970,089) or Quinn (U.S. Patent 4,580,573) (with Weldon U.S. Pat. No. 5,195,990, Carpenter (U.S. Patent 4,586,491), and Kiemeneij (U.S. Pat. No. 6,723,083) allegedly cited as evidence to establish inherent properties of the heart, gaskets and definitions recognized by one of ordinary skill).

Whether claims 19-22, 24, 26, 28, 29, and 32 are unpatentable under 35 U.S.C. 103(a) over Petruzzi (U.S. Pat. 4,474,174) in view of D'Amelio et al. (U.S. Pat. No. 4,659,195), Ueda (U.S. Pat. No. 4,617,914), and Takahashi reference manual.

Whether claims 19-22, 24, 26, 28, 29, and 32 are unpatentable under 35 U.S.C. 103(a) over D'Amelio (U.S. Patent 4,659,195) in view of Ueda (U.S. Patent 4,617,914) further in view of Forester et al (U.S. Patent 4,905,667) or Patel (U.S. Patent 4,577,621).

Whether claims 22 and 29 are unpatentable under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

III. ARGUMENT

The Examiner has cited fourteen (14) separate references in making six separate rejections of the claims. The MPEP, § 706.02 is very clear on this point, stating, “Merely cumulative rejections, i.e., those which would clearly fall if the primary rejection were not sustained, should be avoided.” The same section of the MPEP also states, “Prior art rejections should ordinarily be confined strictly to the best available art.” The number of rejections and references lead to the inescapable conclusion that none of the rejections have merit.

In addition to the multiple rejections mentioned above, two of the rejections are presented in an alternative format (i.e., anticipated or obvious). Each rejection has also been presented as a “blanket rejection” (i.e., lacking explanation as to the relevance of the reference to each claim and an analysis of the elements of the claim in view of that reference). As a result, the grounds of rejection for each claim cannot be ascertained.

Accordingly, the Examiner has failed to provide a prima facie case against patentability of any of the claims. Applicant traverses these rejections, as discussed below, but asserts that the presentation of multiple rejections under alternative theories is merely indicative of the similar devices in the art, not evidence of the present invention.

As set out in detail in Dr. Paskar’s Appeal Brief, the Examiner repeatedly ignored fundamental limitations of the claims. The Examiner’s approach of ignoring claim limitations is fundamentally flawed and is repeated throughout the Office action.

Fundamental to many of the Examiner’s rejections is the fact that he fails to recognize that the claims define the “distal end portion” as planar, which excludes from consideration many if not all of the references and combinations cited by the Examiner.

The Examiner also errs in his conclusions concerning inherency, specifically the Examiner's conclusion that the "out-of-plane" feature of certain of the claims is inherently present in the cited art—viz., Sylvanowicz (discussed in the appropriate sections below). This construction of Sylvanowicz is inconsistent with the claim requirement that the distal end portion of the catheter tube be planar. Moreover, the Examiner's conclusion cannot be true, as shown by the Examiner's actions in one of the parent applications of the present application and as discussed in Dr. Paskar's Appeal Brief. In application Serial No. 07/834,007, the Examiner refused to accept new drawings showing the out-of-plane feature stating:

"The curves that are generated as shown in new figures 13-15B would not necessarily be expected based upon the original disclosure." (p. 2 of Office action dated 11/19/92).

If this was true of applicant's disclosure at the time, it is certainly true of Sylvanowicz. The out-of-plane feature is not inherent and, therefore, Sylvanowicz does not teach the out-of-plane feature of these claims.

In summary, the Examiner in the Office action below routinely ignored claim limitations, mischaracterized the art, and postulated motivation to modify and combine the art where none existed. All the rejections should be reversed.

REJECTIONS UNDER 35 U.S.C. § 102

Whether claims 19-22 are unpatentable under 35 U.S.C. 102(b) over U.S.

Patent 4,430,083 to Ganz et al.

There is a fundamental difference between Ganz et al. and the invention of claims 19-22. These claims all require (1) a “disposing” step and (2) a “forming” step. Ganz et al. discloses a system in which preformed inner catheters are disposed in a catheter tube. There is no “forming” step in Ganz et al. (See Dr. Paskar’s Appeal Brief for a complete discussion.) The invention of claims 19-22 specifically requires this “forming” step, which Dr. Paskar’s disclosure reveals can be accomplished by rotation of the inner element with respect to the outer catheter tube (in fact the only method for “forming” the out of plane shape disclosed by Dr. Paskar is rotation). The elements of the Ganz et al. system, on the other hand, are shaped such that “forming” in this sense is impossible—Ganz et al. is limited to the shape defined by the preformed inner catheters. Once one of the inner catheters is disposed in outer catheter in Ganz et al, it is automatically in the shape controlled by the inner catheter—there is no separate forming step in Ganz et al.

Claim 19 is allowable for this reason. Claims 20-22 depend from and relate back to claim 19 and are allowable therewith. Claim 21 further requires reforming the distal end of the combination catheter into a substantially different shape. Claim 22 depends from claim 21 and further specifies that the reformed combination catheter is used in a medical procedure while the distal end of the combination catheter is in the reformed shape. The Examiner takes the position that Ganz et al. shows these elements as follows: “upon completion of the procedure, the combination catheter would be removed from the

patient this [sic] would entail the reconfiguration of the combination catheter in a catheterization removal medical procedure.” The Examiner’s position is not based upon the Ganz et al. reference or any other source. There is no mention in Ganz et al. of “a catheterization removal medical procedure” and the Examiner has not pointed to any such procedure in the art.

Dr. Paskar, the applicant, is entitled to have his claims examined based upon the art, not on specious medical procedures invented by the Examiner.

The anticipation rejection on this ground should be reversed.

Whether claims 19-22 are unpatentable under 35 U.S.C. § 102(b) as anticipated by (or in the alternative under 35 U.S.C. 103(a)) over Sylvanowicz (U.S. Pat. No. 5,267,982), alone or in view of either Voda (U.S. Pat. No. 5,445,625) or Weldon U.S. Pat. No. 5,195,990) and Kiemeneij (U.S. Pat. No. 6,723,083).

To the extent that this rejection is one under Section 103, applicant hereby incorporates the following argument into the Section 103 section below.

This rejection is fundamentally flawed because it ignores the fact that the claims define the “distal end portion” of the catheter tube as being that portion which “defines a first plane”. The Examiner’s rejection is based upon using portions of the Sylvanowicz outer tube which are out of the plane containing the distal end of that tube, and hence is inconsistent with the claim language of the present application.

As explained in Dr. Paskar’s Appeal Brief, when Sylvanowicz is analyzed properly, using the language of the present claims, no configuration of Sylvanowicz is out-of-plane as defined by the present claims. The Sylvanowicz configurations may be out-of-plane with respect to some arbitrary plane, but none is out of plane with respect to the “first plane” defined by the “distal end portion of the catheter tube”. The fundamental flaw in the Examiner’s rejection is that the distal end portion of the catheter tube extends back from the distal end of the tube only so far as the catheter tube is in a plane. Once the catheter tube moves out of that plane, it no longer defines “a first plane” and hence does not constitute the “distal end portion”.

As explained in detail in Dr. Paskar’s Appeal Brief, it is physically impossible for the Sylvanowicz apparatus to satisfy the requirements of these claims. The distal end portion 62 of catheter tube 52 in Sylvanowicz is straight in Fig. 12 and in Fig. 14, and

there is no indication that the distal end portion 62 is curved at any time in moving from the Fig. 12 position to the Fig. 14 position. In fact, Sylvanowicz specifically identifies portion 62 as “a **straight distal segment** 62 extending from the curved portion 60.” (col. 6, ll. 53-56)(Emphasis added).

Thus, the distal segment of Sylvanowicz **that includes the end**, i.e., the distal end portion, is straight, not curved. Since the distal end portion of the catheter tube in Sylvanowicz is straight, it is incapable of providing the surprising interaction of two curved distal end portions which results in the inner element being thrown out of plane with respect to the outer catheter tube.

The Examiner takes the position that in moving from the Fig. 12 to the Fig. 14 position, the catheter must go out-of-plane, but as explained in Dr. Paskar’s Appeal Brief, that conclusion is false. The present claims clearly define the plane with respect to the **curved distal end portion** of the outer catheter, not with respect to the outer catheter as a whole. It is only by ignoring the plain language of the claim and of Sylvanowicz (“**straight** distal segment 62”) that the Examiner is able to reach his erroneous conclusion as to what must happen.

Furthermore the Examiner recognizes that the configuration of Fig. 12 in Sylvanowicz is planar, but appears to take the position that the other configuration (that of Fig. 14) must be out-of-plane. That conclusion is also false. As explained in detail in Dr. Paskar’s Appeal Brief, formation of the configuration for entering the right coronary artery ostium (the configuration of Fig. 14) involves co-linear elements at the point where the inner catheter exits the outer tube. If the distal portion of the inner catheter points toward the right coronary ostium, and the straight distal segment 62 points toward the

rights coronary ostium (as stated by Sylvanowicz), then those two elements **must be in the same plane**. If they were not co-planar when in the Fig. 14 configuration, it would be physically impossible for both the distal segment 62 of the outer tube and the distal portion of the inner catheter to both point toward the right coronary ostium.

In Sylvanowicz a single plane always contains the straight distal end portion 62 of the catheter tube and curved distal end portion 54 of the inner element, **even as the inner element is rotated from one position to the next**. This differs from the presently claimed invention because the distal end portion 62 of the catheter tube in Sylvanowicz is straight, not curved as required by the present claims. An infinite number of planes pass through the straight distal end portion 62 of the catheter tube in Sylvanowicz, and so in the Fig. 12 and Fig. 14 positions in Sylvanowicz and in all positions in between, the distal end portion 54 of the inner element lies in one of those planes.

The Examiner's position ignores the clear requirement of the present claims that the distal end portion of the catheter tube define a first plane (i.e., be planar in the sense that is used in the present invention). Under the Examiner's construction of Sylvanowicz, the curved portion of Sylvanowicz is included in the "distal end portion". But, during rotation of the inner element with respect to the outer catheter tube in Sylvanowicz, not all of the curved portion of the outer tube remains in the same plane. It is, therefore, not a portion of the "distal end portion" as defined by these claims. Under the express language of claim 19, the portion of Sylvanowicz referred to by the Examiner includes portions which are not planar, and which therefore do not constitute the required plane-defining distal end portion.

The presently claimed invention is immensely useful. It permits two planar elements (the inner element and the outer tube) to interact to provide an out-of-plane position for the distal end. Yet Sylvanowicz fails to even hint at this feature. The claimed feature is simply not inherent in Sylvanowicz.

The Examiner's inherency argument is further undercut by the history of the present invention. In Serial No. 07/834,007, one of the parent applications of the present application, the Examiner refused to accept new drawings showing the out-of-plane feature stating:

“The curves that are generated as shown in new figures 13-15B would not necessarily be expected based upon the original disclosure.” (p. 2 of Office action dated 11/19/92).

If this was true of applicant's disclosure at the time, it is certainly true of Sylvanowicz. Sylvanowicz simply does not teach the out-of-plane feature of these claims.

The Examiner is simply wrong. He has ignored claim limitations fundamental to the claimed invention, and he has “found” inherency where none in fact exists. These claims are allowable over Sylvanowicz for all these reasons.

The various secondary references cited by the Examiner (which would appear to be extremely inappropriate in an anticipation rejection) do not add anything to the rejection. In fact, one reference, Kiemeneij, has a filing date over a year later than that of the present application of Dr. Paskar. Such a reference cannot be of relevance. Moreover, Kiemeneij suffers from the same fundamental flaw discussed above—the “distal end portion” of the presently claimed invention must (by the terms of the claims themselves) lie in a first plane. Whether other uses of the phrase “distal end portion” are

possible is irrelevant since the present claims require that the “distal end portion” define the first plane. Voda suffers from the same deficiency. Weldon does not add anything which changes the conclusion that, when these claims are properly read, they are not anticipated (or rendered obvious) by Sylvanowicz.

Claim 19 is an independent claim that requires “forming the combination catheter into a shape in which the distal end of the combination catheter is disposed substantially **out of the first plane** for a period of time sufficient to permit medical use of at least one of the catheter tube or the inner medical element.” As explained above, Sylvanowicz does not have the out-of-plane feature as claimed, and has no suggestion of using a catheter having such an out-of-plane configuration in a medical way.

Claims 20, 21, and 22 depend from claim 19 and are allowable therewith.

For all these reasons, these claims are all allowable over Sylvanowicz.

Whether claims 22, 24, 26, 28, 29, and 32 are unpatentable under 35 U.S.C. § 102(b) as anticipated by (or in the alternative under 35 U.S.C. 103(a)) over Sylvanowicz (U.S. Pat. No. 5,267,982), alone or in view of either Weldon U.S Pat. No. 5,195,990, Quinn (U.S. Patent 4,580,573), Carpenter (U.S. Patent 4,586,491), Saice (U.S. Patent 3,970,089) and Kiemeneij (U.S Pat. No. 6,723,083).

To the extent that this rejection is one under Section 103, applicant hereby incorporates the following argument into the Section 103 section below.

Claim 22 was discussed in the section immediately above. Quinn and Carpenter are not believed to address the deficiencies set out above with respect to the rejection of claim 22. The Examiner simply repeats his inaccurate understanding of the claimed “distal end portion” in this rejection.

Claims 24, 26, and 32 depend from claim 19 and are allowable therewith. Claims 24 and 26 require proximal fixing, which, as explained in detail in Dr. Paskar’s Appeal Brief, is not shown in Sylvanowicz (which reference provides for both translation and rotation while the hemostasis valve is operating). More importantly, Sylvanowicz completely lacks the claimed out-of-plane feature. Claim 24 requires “proximally fixing the distal end of the combination catheter substantially out of the first plane.” Sylvanowicz has no such out-of-plane configuration, as explained above.

Claim 28 is another independent claim. This claim includes the fixing feature and is allowable for the same reasons as claims 19, 24 and 26. Sylvanowicz and the six secondary references completely lack the claimed out-of-plane feature as defined by this claim.

Claim 29 is also independent and includes the out-of-plane and fixing requirements of claim 28. The Examiner takes the position that Voda requires “multiple out of plane configurations during dual angiography.” As explained above, however, Sylvanowicz performs such a procedure with NO out of plane shapes as defined by these claims. Voda does not suggest any modification to Sylvanowicz which would change that. Claim 29 is allowable for all these reasons.

Claim 32 depends from claim 19 and is allowable with that claim. Claim 32 is also allowable because it specifies that the forming step (in which the distal end of the combination catheter is disposed substantially out of the first plane) includes rotating the inner medical element with respect to the catheter tube. The references are silent as to such a feature.

The Examiner also (see page 13 of the Examiner’s Answer) has a reference to “claims 21 and 22” in discussing this rejection. Since this rejection does not address claim 21, it is assumed that the reference to claim 21 is in error. In any event, claim 21 relates back to claim 19 which, as described above, is allowable over this art.

For all these reasons, these claims are all allowable over Sylvanowicz.

REJECTIONS UNDER 35 U.S.C 103(a)

Whether claims 24, 26, 28, and 32 are unpatentable under 35 U.S.C. § 103(a) over U.S. Patent 4,430,083 to Ganz et al. in view of U.S. Patent 3,970,089 to Saice.

The Examiner's Answer with respect to this rejection refers to claims 12, 14, 16 and 31—none of which are the subject of the present rejection. In fact, the only claim which is the subject of this rejection which is referred to by the Examiner in his Answer is claim 32. The rejection of the other claims should be summarily reversed. If the Examiner is merely restating his prior position below, then Dr. Paskar, the current applicant, stands on his argument set forth in the Appeal Brief.

Claim 32 depends from claim 19 and provides that the “forming step includes rotating the inner medical element with respect to the catheter tube.” As discussed above in connection with the Ganz et al anticipation rejection, Ganz et al does not teach a separate forming step as required by these claims. The Saice reference is not alleged by the Examiner to provide that missing element.

In fact, the Saice reference appears to be cited for the use of proximal fixing of the inner element against the outer catheter tube, an element that is required by the present claims 24, 26 and 28. Why this combination should be obvious is unclear given that the shapes of the Ganz et al inner and outer members provide for “distal” fixing of the combination catheter shape, as opposed to the “proximal” fixing required by the present claims. Why would one combine Saice with Ganz et al to provide (proximal) fixing when Ganz et al already provides (distal) fixing? Nothing in the art suggests that this combination could possibly be desired.

Proximal fixing, as required by these claims, is irrelevant to the system of Ganz.

Whether claims 19-22, 24, 26, 28, 29, and 32 are unpatentable under 35 U.S.C. 103(a) over Petruzzi (U.S. Pat. 4,474,174) in view of D'Amelio et al. (U.S. Pat. No. 4,659,195), Ueda (U.S. Pat. No. 4,617,914), and Takahashi reference manual.

The Examiner's fundamental flaw in this rejection is the assumption that one can look in one direction and blindly hit a target located in another direction—a feat that would have eluded Annie Oakley on her best day.

Petruzzi is explained in detail in Dr. Paskar's Appeal Brief. In summary the drawings of Petruzzi, namely Fig. 1, which hide the opening in the endoscope that faces the ampulla of Vater are inconsistent with the Examiner's speculation of an out-of-plane configuration but are totally consistent with a manipulation which result in the distal end, the window, and the guiding catheter of Petruzzi being "in plane", not out-of-plane as required by these claims. As stated in Dr. Paskar's Appeal Brief, the affidavit of Dr. Giuseppe Aliperti, filed with the Amendment dated November 4, 2005, reveals that the Examiner's construction of Petruzzi is incorrect and totally inconsistent with actual devices, whereas the applicant's construction of Petruzzi is totally consistent with real world devices. This evidence, which is unrebutted, conclusively establishes that the Examiner has misconstrued Petruzzi and that the rejection thereon should be reversed. The only reasonable interpretation of Petruzzi is that both the enter and outer elements are in the same plane, which makes it possible to both visualize and intubate the ampulla of Vater.

Moreover, the claimed out-of-plane shape of the distal end in Petruzzi, as explained in Dr. Paskar's Appeal Brief, is unachievable since the distal end of Petruzzi is straight, solid, and unbendable. See Fig. 3 of Petruzzi. There is absolutely no

mechanism in Petruzzi to cause the distal end portion to bend in any way. It is solid. The inner catheter that comes out of the side of this straight, solid portion is bendable by the wedge 92, but there is no similar mechanism for forming a curve in the distal end portion of the outer tube. Note as well that the movement of element 82 in Petruzzi is in the plane of the window of the outer catheter. It appears that the structure of Petruzzi, as would be expected, mechanically confines element 82 to stay in plane. Moreover, there is absolutely no structure provided to move element 82 out of that plane.

As explained in Dr. Paskar's Appeal Brief, with the apparatus of Petruzzi, the only way to direct the catheter to the ampulla of Vater is by pointing the window of the endoscope straight toward the ampulla. This is a matter of basic physics. If the window were not pointing at the ampulla, the user would not have any idea where to direct the catheter. And if the catheter were disposed out-of-plane with respect to the window/ampulla plane, it would not (could not) go into the ampulla.

Claim 19 is an independent method claim that requires the defined out-of-plane feature. As explained above, Petruzzi completely lacks this feature. Claims 20-22, 24, and 26 depend from or relate back to claim 19 and are allowable therewith. In addition, claim 20 includes the step of positioning the combination catheter in a desired position, and using the combination catheter in a medical procedure while the distal end of the combination catheter is disposed substantially out of the first plane. None of the cited references disclose the out-of-plane feature, so they by definition lack the feature of using the combination catheter in a medical procedure while the distal end of the combination catheter is out-of-plane.

The Examiner takes the position that Petruzzi could be modified by D'Amelio to overcome the deficiencies in the Petruzzi reference. This ignores the fundamental problem with D'Amelio as a reference: D'Amelio expressly teaches against forming out-of-plane shapes. In connection with Fig. 19, D'Amelio et al. expressly teaches that “objective assembly 46 **must articulate in the same plane** as the guide member 36.” Col. 8, lines 37-39. D'Amelio et al., therefore, teaches directly away from the invention claimed in claim 19. D'Amelio et al. not only teaches it—it demands it, stating that the inner assembly “must” articulate in the same plane as the outer assembly. For all these reasons, any rejection founded upon D'Amelio et al. is baseless. Even if one were to make the combination of Petruzzi and D'Amelio as suggested by the Examiner, one would not get the presently claimed invention, because D'Amelio teaches directly against it. Ueda adds nothing to overcome the deficiencies in the Petruzzi/D'Amelio art.

As explained in Dr. Paskar's Appeal Brief, these claims are all allowable over these references.

Whether claims 19-22, 24, 26, 28, 29, and 32 are unpatentable under 35 U.S.C. 103(a) over D'Amelio (U.S. Patent 4,659,195) in view of Ueda (U.S. Patent 4,617,914) further in view of Forester et al (U.S. Patent 4,905,667) or Patel (U.S. Patent 4,577,621).

D'Amelio et al. is fundamentally different from the presently claimed invention. Most significantly, as pointed out above, D'Amelio et al. expressly teaches against forming out-of-plane configurations. All the claims of the present application require out-of-plane configurations. Hence all of these claims are allowable over D'Amelio.

Moreover, there are numerous other differences over this reference set forth in detail in Dr. Paskar's Appeal Brief. Dr. Paskar accomplishes more with inner and outer formable tubes than D'Amelio accomplishes with a much more complicated apparatus.

Preliminarily, it should be noted that there is nothing in D'Amelio et al. which would motivate one of ordinary skill in the art to make any modifications to the D'Amelio et al. apparatus whatsoever. The apparatus appears to adequately solve the problems at hand, and there are no hints of any deficiencies in D'Amelio et al. Moreover, the Examiner has not pointed to anything in other prior art which would suggest making any modifications to D'Amelio et al.

The Examiner also cites Ueda for braking systems to maintain articulated curves. Although that may be true in the abstract, it is hardly true in the context of the present rejection which includes D'Amelio et al. D'Amelio et al., when correctly read, teaches free rotation because that is how it works—a can is entered and the device is spun through 360 degrees to inspect the can. The combination is simply inconsistent with the primary reference.

Claim 19 is an independent claim that specifies forming the combination catheter into a shape in which the distal end of the combination catheter is disposed substantially out of the first plane for a period of time sufficient to permit medical use of at least one of the catheter tube or the inner medical element. This is totally inconsistent with the express teaching of D'Amelio. Claim 19 is, therefore, allowable.

Claims 20-22, 24 and 26 all relate back to claim 19 and are allowable for the same reasons as that claim. Claim 24, in addition, requires proximally fixing the distal end of the combination catheter substantially out of the first plane. Since D'Amelio teaches away from forming such an out-of-plane shape, it also teaches away from fixing the combination catheter in that shape. Claim 26 also provides for proximally fixing the inner medical element against translation and rotation with respect to the catheter tube. As discussed in Dr. Paskar's Appeal Brief, D'Amelio et al. fixes against translation but not rotation. In fact fixation against rotation is undesirable in D'Amelio et al. as explained in the Appeal Brief. Claims 24 and 26 are allowable for these reasons as well.

Claim 28 is another independent claim. It includes the out-of-plane feature discussed above in connection with claim 19, and the proximal fixing against rotation (and translation) feature discussed above in connection with claim 26. It is allowable over these references, therefore, for the same reasons as both those claims.

Claim 29 is an independent claim that requires not only the forming of a first out-of-plane configuration, but also a second. It also requires proximal fixation against rotation (and translation) during those times when the distal end portion of the combination catheter is in the first out-of-plane configuration, and during those times when it is in the second out-of-plane configuration. The cited references do not teach a

single out-of-plane configuration, much less two. Nor does this combination teach the requisite proximal fixing against rotation. Claim 29 is allowable for all these reasons.

Claim 32 depends from claim 19 and is allowable for the same reasons as that claim.

REJECTIONS UNDER 35 U.S.C. § 112

Whether claims 22 and 29 are unpatentable under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

The Examiner has rejected claims 22 and 29 under Sec. 112 for an alleged failure of the specification to describe the invention in such a way as to reasonably convey to one skilled in the relevant art that the inventor had, at the time the application was filed, possession of the claimed invention.

The present application has the same disclosure as that found in the parent application that is now U.S. patent 6,623,449. That disclosure provides as the fourth object:

“A fourth object is the provision of such a catheter which can mimic almost any catheter configuration, and can **thereafter be reformed in the body to other desired shapes.**”

A primary goal of the present invention, therefore, is clearly stated to be the reformation of the catheter from one “desired shape” to another “desired shape”.

The Examiner admits that figures 15 and 15a disclose an “out of plane shape” but conveniently ignores the fact that Fig. 15b discloses a **plurality** of out-of-plane shapes. It is physically impossible for the Examiner to have looked at Fig. 15a and not seen Fig. 15b. What then can be the purpose of the plurality of out-of-plane shapes shown in Fig. 15b? The specification provides that whole families of these “desired shapes” can be out of plane, as shown in the following passage:

“Again, a whole family of these "out of plane" curves can be achieved as desired by the user by curving the sheath more or less and exposing more or less of the inner catheter or element. See FIG. 15B.”

As explained in Dr. Paskar’s Appeal Brief, the whole purpose of a “desired shape” in a catheter is to use that “desired shape” in a medical procedure—otherwise there is no good reason for forming the desired shape.

As an example, one of the goals of the present invention is to easily and simply reshape a catheter to sequentially catheterize multiple cerebral and visceral branch arteries, as revealed in the following passage of the disclosure (again referring to the ‘449 patent disclosure for ease of reference):

“Selective catheterization of cerebral and visceral branch arteries is often difficult and at times impossible in some patients--particularly older patients with very tortuous and ectatic vasculature. Successful catheterization sometimes requires multiple catheter exchanges for various shaped catheters. It is not uncommon to easily catheterize three of four vessels for a four vessel head study, only to find that the fourth vessel (generally the left or right carotid) requires an entirely different catheter shape and tip orientation. **It would be desirable if one could easily and simply reshape the catheter and reorient the tip to direct it into the vessel orifice, instead of depending on several complex catheters that require reformation, fancy torque and advancing maneuvers, body english and, above all, luck.**” (col. 1, lines 29-42).

The § 112 rejection should be reversed.

Comments on Examiner's Response to Argument

1. The Examiner raises objection to Dr. Paskar's reference to the earlier specification in providing support for the claim language. It is respectfully submitted that failure to reference the earlier of two specifications by Dr. Paskar could have resulted in a "new matter" rejection which (since the relevant disclosure was present in both specifications) would have simply involved an additional waste of time for response.

The Examiner also takes issue with Dr. Paskar's discussion of inherency in his Appeal Brief in connection with application Serial No. 07/834,007. The Examiner now appears to be taking the position that the basis for the refusal to accept new drawings showing the out-of-plane feature was that the "specific relative sizes of the various shapes would not have been apparent to one of ordinary skill in the art." Of course, drawings are not production specifications, so the specific relative sizes of the curved shapes shown was, and continues to be, irrelevant. Prior to this rewriting of history, the position the Examiner took was that:

"The curves that are generated as shown in new figures 13-15B would not necessarily be expected based upon the original disclosure." (p. 2 of Office action dated 11/19/92).

This is directly relevant to the issue of inherency.

2. On page 20 of the Examiner's Answer the Examiner appears to take the position that the fact that Dr. Paskar abandoned a previous appeal constitutes some sort of delay on his part. In fact, three patents issued from cases based upon that abandoned appeal, including 78 patent claims. What this reflects is Dr. Paskar's continuing attempt to satisfy the Examiner's objections. If these claims were allowable after the previous

appeal was abandoned, why was Dr. Paskar forced to file the previous appeal in the first place? Dr. Paskar continues to try to simplify the issues in connection with his inventions, but continues to be met with multiple rejections citing multiple pieces of prior art.

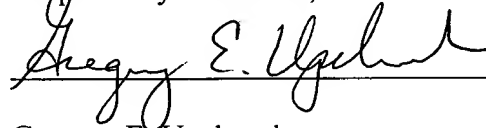
The Examiner's comments on the references are discussed above in connection with each rejection.

CONCLUSION

Six rejections using fourteen references speaks eloquently to the fact that the Examiner has not, and cannot, find the presently claimed inventions in the prior art.

Reversal of the Examiner, therefore, is solicited.

Respectfully submitted,

A handwritten signature in black ink, reading "Gregory E. Upchurch", is written over a horizontal line.

Gregory E. Upchurch
Reg. No. 28,482
c/o LegalMetric, Inc.
1000 Des Peres Road, Suite 210
St. Louis, MO 63131
314-965-3001
Fax: 314-754-9950